



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,007	12/21/2000	Therese Ouellet	411044.90030	2935

7590 10/03/2002
Nicholas J. Seay
Quarles & Brady LLP
P O Box 2113
Madison, WI 53701-2113

EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
----------	--------------

1636

DATE MAILED: 10/03/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/747,007

Applicant(s)

OUELLET ET AL.

Examiner

David Lambertson

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/25/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 20-27 and 37-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 28-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims 20-27 and 37-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Applicant's election with traverse of Group I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the subject matter of the restriction groups are inextricably linked. Furthermore, applicant indicates that it would be unnecessarily burdensome on both the applicants and the Office to maintain the restriction groups as initially defined due to the fact that the SEQ ID NOS which have been separated are closely related.

This is not found persuasive because the nucleic acids (or fragments thereof) can be used for a number of different reasons, one example being as primers for the amplification of genes. Therefore the sequences are not inextricably directed towards a method of mediating translational activity, as indicated in Group III, nor are they inextricably directed towards a method of increasing the amount of protein in an organism, as indicated in Group IV, or the generation of a transgenic host cell line, as indicated in Group II, for the same reason. In addition, each of these methods can be performed without the use of the sequences disclosed by applicant. In terms of the burden of searching nucleic acids, pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences listed in the claims are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of

Art Unit: 1636

such nucleotide sequences to be claimed in a single application. Under this policy, a single independent and distinct nucleotide sequence will be examined in a single application.

The sequences are considered to be unrelated since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique nucleotide sequence, even though they differ by only 3 nucleotides. Furthermore, a search of more than one (1) of the sequences claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination.

Concerning the claims which refer to transgenic animals, these claims are also found to be separate inventions than the nucleic acids as claimed. A transgenic animal can be generated using any nucleic acid, and does not require the nucleic acids as disclosed in the instant application. Therefore, the nucleic acids and the transgenic animals are still found to be patentably distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

Concerning claims 3, 7-14 and 29-36, these claims refer to non-elected subject matter as they relate to a non-elected sequence. As such, these claims cannot be examined under the elected conditions, and require cancellation.

Claims 1, 2, 4-6, 15-19 and 28 are subject to examination in the instant application. Also, applicant is required to cancel the non-elected subject matter in the elected claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-6, 15-19 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant claims "An isolated nucleic acid comprising a nucleotide sequence selected from...SEQ ID NO: 6, or a fragment, derivative or analog thereof...". Applicant defines a fragment, derivative or analog thereof as an element that exhibits "from about 70% similarity to the nucleotide sequence of, for example but not limited to, SEQ ID NOS 5 to 9, or...that hybridize to the above listed nucleotide sequences...". In the claims, applicant uses "comprising" to define the limitation of a fragment, analog or derivative thereof, with respect to SEQ ID NO: 6. Because "comprising" constitutes "open-type" language, the fragment can contain more than just the sequence described as SEQ ID NO: 6. Since a fragment, derivative or analog can exhibit 70% similarity to any number of sequences, a fragment, derivative or analog comprising SEQ ID NO: 6 can read on an infinite number of nucleotide sequences so long as SEQ ID NO: 6 is within those sequences. Therefore applicant's claims read on a genus of sequences that comprise SEQ ID NO: 6.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical

Art Unit: 1636

properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, applicant has not described a sufficient number of examples of fragments comprising SEQ ID NO: 6, having not defined an endpoint encompassed by the terms "fragment, derivative or analog thereof". Thus, a fragment comprising SEQ ID NO: 6 can encompass a sequence that has not been described in the instant application. Therefore, applicant has not disclosed a representative number of species by actual reduction to practice, and has not satisfied the written description requirement.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5, 6, 15-19 and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,824,872 (henceforth the '872 patent). Although the conflicting claims are not identical, they

Art Unit: 1636

are not patentably distinct from each other because applicant is claiming a genus of sequences wherein a species in said genus has already been patented.

The claims of both the instant application and the '872 patent are claiming the same sequence. Claims 1-3 of the '872 patent claim SEQ ID NO: 1 and its use in a construct for expressing a gene. SEQ ID NO: 1 contains, with 100% identity, SEQ ID NO: 6 which is claimed in the instant application. Because the instant application uses the "open-type" language in claiming the sequence, the claim reads on any sequence wherein SEQ ID NO: 6 is included, which can be an infinite number of sequences, one of which is SEQ ID NO: 1 of the '872 patent. The translational regulatory property of SEQ ID NO: 6 would be inherent to SEQ ID NO: 1, owing that the sequences are identical within the scope of the claims, therefore that property cannot make the sequences patentably distinct from each other. Therefore the claims to a sequence comprising SEQ ID NO: 6 in the instant application, claims 1, 2, 5, 6 and 15-17 are anticipated by claim 1 of the '872 patent. Also, claims 18, 19 and 28 of the instant application read on a construct comprising SEQ ID NO: 6 which is anticipated by the construct disclosed in claims 2 and 3 of the '872 patent in light of the same rationale.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(f) he did not himself invent the subject matter sought to be patented.

Art Unit: 1636

Claims 1, 2, 4-6, 15-19 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Miki, et al. (US Patent No. 5,824,872; henceforth Miki).

Applicant's invention concerns an isolated nucleic acid sequence, specifically SEQ ID NO: 6, and fragments, derivatives or analogs thereof (claims 2 and 15-17). In some instances these sequences are indicated to have translational regulatory activity (claims 1, 5 and 6). Applicant also claims sequences that hybridize to this sequence (claim 4), and constructs which comprise the sequences or fragments thereof in operative association with genes of interest and one or more regulatory elements (claims 18, 19 and 28). Applicant's definition of translational regulatory activity, as indicated on page 18, line 24 to page 19, line 2 of the instant application, is an element that modulates the amount of protein in a host, which can be operatively associated with promoter elements. In the broadest interpretation of the definition, it encompasses transcriptional elements, which are necessary to modulate the amount of protein in a host as no protein can be produced in the absence of transcription.

Miki claims a sequence, a portion of which is 100% identical to SEQ ID NO: 6 of the instant application, having constitutive promoter activity (in terms of transcription) in claim 1 of US Patent No. 5,824,872. Due to the "open-type" language of the claims of the instant application, Miki anticipates claims 1, 2, 5, 6 and 15-17 of the instant application. Miki further claims a vector comprising the sequence operatively linked to a gene of interest, where constitutive expression is desired for the gene of interest, in claim 3 of US Patent No. 5,824,872, thereby anticipating claims 18, 19 and 28 of the instant application. Miki also discloses that sequences that are substantially homologous, which can be identified by hybridization

Art Unit: 1636

techniques, are also encompassed by the invention (see column 4, lines 41-46), thereby anticipating claim 4 of the instant application.

In the event applicant chooses to argue that the definition of translational regulatory activity does not encompass transcriptional regulatory activity, applicant is respectfully reminded that due to the 100% sequence identity between the sequence of Miki and SEQ ID NO: 6, the activity as claimed by applicant would be an inherent activity of the molecule, and remain anticipated by Miki.

Claims 1, 2, 4-6, 15-19 and 28 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The subject matter has been patented in US Patent No. 5,824,872 by a different inventive entity and with a different assignee than those indicated on the instant application.

Allowable Subject Matter

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305-1998. The fax phone numbers for the

Art Unit: 1636

organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
September 27, 2002

DAVID GUZO
PRIMARY EXAMINER
David Guzo